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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 08/823,980 | 03/25/1997 | AMY J. WEINER | CHIR-0108 | 8052 |

7590 11/17/2004

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| EXAMINER |
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SCHWADRON, RONALD B

| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/823,980

Applicant(s)

WEINER ET AL.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-44, 52, 55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 41-44, 52, 55, 56 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

1. Claims 41-44,52,55,56 are under consideration.
2. The rejection of claim 53 as provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 51 of copending Application No. 08/437952 is withdrawn in view of the cancellation of said claim
3. Regarding the double patenting rejections in paragraphs 5-7 of the previous Office action, while said rejections were formulated and explained as obviousness type double patenting, reference was incorrectly made to Schneller type double patenting. Said rejections were intended as obviousness type. Applicant responded to the rejections as obviousness type double patenting.
4. The rejection of claims 41-44,52,55,56 and 53 as provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21,47,51,54 of copending Application No. 08/437952 is withdrawn in view of the TD filed 8/23/2004 and the cancellation of claim 53.
5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 41-44,52,55,56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43,44,47,48,50,51 of copending Application No. 08/438183. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The two sets of claims are drawn to immunogenic compositions/peptides versus immunogenic compositions which differ in scope but contain the same peptide/peptide conjugates. The peptide of SEQ. ID. NO:8 is derived from HCV and is the same in both applications. The agents of claims 43 and 44 are well known in the art as linking agents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Regarding applicants comments, the MPEP section 804.02, part IV. states:

IV. DISCLAIMING MULTIPLE DOUBLE PATENTING REFERENCES

If multiple conflicting patents and/or pending applications are applied in double patenting rejections made in a single application, then prior to issuance of that application, it is necessary to disclaim each one of the conflicting double patenting references applied, rather than disclaiming only the conflicting double patenting reference with the earliest issue date (assuming at least one of the references is a patent). A terminal disclaimer fee is required for each terminal disclaimer filed. To avoid paying multiple terminal disclaimer fees, a single terminal disclaimer may be filed, wherein all the conflicting double patenting references are disclaimed therein.

Disclaiming each one of the conflicting double patenting references is necessary to avoid the problem of dual ownership of patents to patentably indistinct inventions in the event that the patent issuing from the application being examined ceases to be commonly owned with any one of the double patenting references that have issued or may issue as a patent. Note that 37 CFR 1.321(c)(3) requires that a terminal disclaimer "[i]nclude a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the rejection."

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 42-44,55 lack antecedent basis in the recitation of "immunogenic polypeptide" because claim 41 is drawn to a fusion protein, not an "immunogenic polypeptide". The claims should be amended to read on a fusion protein. For example, claim 42 could be amended to read "fusion protein of claim 41 wherein the immunogenic polypeptide is linked ...".

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644


RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 1600